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JEFFREY M. GREENMAN
BAYER PHARMACEUTICALS CORPORATION
400 MORGAN LANE
WEST HAVEN, CT 06516

EXAMINER
HA, JULIE

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/500,680	WANG ET AL.	
	Examiner	Art Unit	
	Julie Ha	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 June 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-65* is/are pending in the application.

4a) Of the above claim(s) *9,14,21,27,38,47 and 54-65* is/are withdrawn from consideration.

5)☒ Claim(s) *11-13,15 and 16* is/are allowed.

6)☒ Claim(s) *1,2,4-8,10,17,19,20,22-26,34-37,39,41-46 and 50* is/are rejected.

7)☒ Claim(s) *3, 18, 26, 28-33, 40, 48-49 and 51-53* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Election/Restriction filed on June 04, 2007 is acknowledged. Claims 1-65 are pending in this application.

Restriction

1. Applicant's election with traverse of species of PACAP for peptide hormone superfamily; adrenocorticotropic hormone for peptide; zinc for salt of transition metal; DMSO for organic salt; acid for dried mixture; and HCl for an inorganic acid in the reply filed on June 04, 2007 is acknowledged. The traversal is on the ground(s) that the species identified by the Examiner are not species of the invention. The Applicants argue that claims 1, 2, 17, 26, and 34 relate to stabilized peptide formulations; claims 1 and 11 recite formulations in either a solution or a suspension; claims 17, 26 and 34 recite stabilized formulations in the form of dried mixtures, and thus the Examiner should have considered these independent claims in making her determination whether unity of invention is present or not. This is not found persuasive because the species are patentably independent and distinct and not coextensive. For example, the special technical feature of claim 1 is a stabilized peptide formulation, either in a solution or in a suspension, comprising: (a) a peptide containing at least one histidine residue; (b) a transition metal salt; and (c) a pharmaceutically acceptable organic solvent. Gockel et al (Inorganica Chimica Acta, July 2001, 323: 16-22) teach a cyclic dipeptide species of composition in the presence of zinc nitrate (see abstract). Gockel et al further teaches (c-HisHis)$ZnCl_2$ (see p. 19, left column, compound 1) and that all species resulting from

reactions of c-HisCys and c-CysCys with zinc salts were insoluble precipitates of indefinite composition. Only in one case could a specific composition be achieved reproducibly: zinc iodide, c-HisCys and triethylamine in ethanol yielded compound $(c\text{-}HisCys)_3Zn_2I$ (see p. 19, bottom of the left column and top of right column). Suspension in chemistry is a heterogenous mixture in which the particles of at least one component are larger than 1mM in at least one dimension, and will eventually settle. Since the dipeptide having at least one histidine residue, with zinc salts in ethanol meets the limitation of claim 1, breaking the unity. The search for each of the inventions is not co-extensive particularly with regard to the literature search. Burden consists not only of specific searching of classes and subclasses, but also of searching multiple databases for foreign references and literature searches. Burden also resides in the examination of independent claim sets for clarity, enablement, and double patenting issues. Further, a reference that would anticipate the invention of one group would not necessarily anticipate or even make obvious another group. Finally, the consideration for patentability is different in each case. Thus, it would be an undue burden to examine all of the above species in one application and the election of species for examination purposes as indicated above is deemed proper. Furthermore, it appears that the Applicants are indicating that the species are not patentably independent and distinct. The Applicants argue that the species identified by the examiner are not species of the invention. If prior art was found on a peptide formulation comprising cobalt and PACAP, this would not render obvious or anticipate a peptide formulation comprising zinc and PACAP, therefore, the species are independent and patentably distinct from each other.

However, noted in the previous office action, **"Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the species unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other species."** If this is the case as Applicants are indicating, the Applicants are hereby requested to state on the record that the species claimed are obvious variants of one another and prior art teaching a peptide formulation having the claimed species formulation would render obvious and anticipate the invention.

The requirement is still deemed proper and is therefore made FINAL. Claims 9, 14, 21, 27, 38, 47 and 54-65 are withdrawn from further consideration as being drawn to nonelected species. Claims 1-8, 10-13, 15-20, 22-26, 28-37, 39-46, 48-53 are examined on the merits in this office action.

Objection-Minor Informalities

2. The title is objected to because the title is too long. The title is limited to 2-7 words maximum. A new title is required that is clearly indicative of the invention to which the claims are directed.

Rejection-35 U.S.C. 112, 1st

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 1-2, 4-8, 10 and 17, 19-20 and 22-25 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The MPEP states that the purpose of the written description requirement is to ensure that the inventor had possession, as of the filing date of the application, of the specific subject matter later claimed by him. The courts have stated:

"To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention." Lockwood v. American Airlines, Inc., 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (1997); In re Gosteli, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) (" [T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." Lockwood, 107 F.3d at 1572, 41 USPQ2d at 1966." Regents of the University of California v. Eli Lilly & Co., 43 USPQ2d 1398.

5. The MPEP lists factors that can be used to determine if sufficient evidence of possession has been furnished in the disclosure of the Application. These include "level of skill and knowledge in the art, partial structure, physical and/or chemical properties, functional characteristics alone or coupled with a known or disclosed correlation between structure and function, and the method of making the claimed invention. Disclosure of any combination of such identifying characteristics that distinguish the claimed invention from other materials and would lead one of skill in the art to the conclusion that the applicant was in possession of the claimed species is sufficient." MPEP 2163.

6. Further, for a broad generic claim, the specification must provide adequate written description to identify the genus of the claim. In Regents of the University of California v. Eli Lilly & Co., the court stated:

"A written description of an invention involving a chemical genus, like a description of a chemical species, 'requires a precise definition, such as by structure, formula, [or] chemical name,' of the claimed subject matter sufficient to distinguish it from other materials. Fiers, 984 F.2d at 1171, 25 USPQ2d at 1606; In re Smythe, 480 F.2d 1376, 1383, 178 USPQ 279, 284-85 (CCPA 1973) ("In other cases, particularly but not necessarily, chemical cases, where there is unpredictability in performance of certain species or subcombinations other than those specifically enumerated, one skilled in the art may be found not to have been placed in possession of a genus. . . ."). Regents of the University of California v. Eli Lilly & Co., 43 USPQ2d 1398.

7. The MPEP further states that if a biomolecule is described only by a functional characteristic, without any disclosed correlation between function and structure of the sequence, it is "not sufficient characteristic for written description purposes, even when accompanied by a method of obtaining the claimed sequence." MPEP 2163. The MPEP does state that for generic claim the genus can be adequately described if the disclosure presents a sufficient number of representative species that encompass the genus. MPEP 2163. If the genus has a substantial variance, the disclosure must describe a sufficient variety of species to reflect the variation within that genus. See MPEP 2163. Although the MPEP does not define what constitute a sufficient number of representative, the Courts have indicated what do not constitute a representative number species to adequately describe a broad generic. In Gostelli, the Court determined that the disclosure of two chemical compounds within a subgenus did not describe that subgenus. In re Gostelli, 872 F.2d at 1012, 10 USPQ2d at 1618.

8. In the instant case, the claims are drawn to a stabilized peptide formulation, either in a solution or in a suspension, comprising: (a) a peptide containing at least one

histidine residue; (b) a transition metal salt; and (c) a pharmaceutically acceptable organic solvent and a stabilized peptide formulation, comprising a dried mixture of an acid and a peptide containing at least one asparagine residue (claims 1 and 17) and a formulation wherein said peptide is selected from group consisting of the peptide hormone superfamily, including glucagons and functionally equivalent variants thereof. The generic statements a stabilized peptide formulation comprising a peptide containing at least one histidine residue and at least one asparagine residue and functionally equivalent variants thereof of glucagon do not provide ample written description for the compounds since the claims do not describe a single structural feature. The specification does not clearly define or provide examples of what qualify as compounds of the claimed invention.

9. As stated earlier, the MPEP states that written description for a genus can be achieved by a representative number of species within a broad generic. It is unquestionable claims 1 and 17 are broad generics with respect all possible compounds encompassed by the claims. The possible structural variations are limitless to any class of peptide or a peptide-like molecule that can form peptide bonds. It must not be forgotten that the MPEP states that if a peptide is described only by a functional characteristic, without any disclosed correlation between function and structure of the sequence, it is "not sufficient characteristic for written description purposes, even when accompanied by a method of obtaining the claimed sequence." MPEP 2163. Here, though the claims may recite some functional characteristics, the claims lack written description because there is no disclosure of a correlation between function and

structure of the compounds beyond compounds disclosed in the examples in the specification. Moreover, the specification lack sufficient variety of species to reflect this variance in the genus since the specification does not provide any examples of derivatives. The specification is void of organic molecules that functions as a peptide-like molecule that qualify for the functional characteristics claimed as a peptide or a peptide-like molecule or other peptidic molecules, and other synthetic peptide or peptide-like molecule that can form peptide bonds.

10. The specification is limited to the peptide or peptide-like molecules that belong to the same class of protein, PACAP, PACAP-like peptides, VIP, glucagons, glucagons-like peptides, secretin, helodermin, and exendin-4. The working example describes the PACAP-66 (see paragraph [0041]). The specification does not describe any other peptides that contain at lest one histidine residue or contain at least one asparagine residue, such as the dipeptide disclosed by Gockel et al (see above), tripeptides disclosed by Pickart Patent (US Patent # 5120831), or the peptide containing at least one asparagine disclosed by Krstenansky patent (US Patent #5834433). Description of PACAP 66 is not sufficient to encompass numerous other peptides that belong to the same genus, a peptide formulation comprising a peptide containing at least one histidine residue and a peptide containing at least one asparagine residue. For example, there are varying lengths, varying amino acid compositions, and numerous distinct qualities that make up the genus. For example, PACAP 66 contains 31 amino acid lengths peptide sequence. Other PACAP sequences contain 176 amino acids (see GenBank Accession # AAB21470), 38 amino acids (see GenBank Accession #

AAB20402), and 195 amino acids (see GenBank Accession # CAA55684). Additionally, there are 20 naturally occurring amino acids, non-natural amino acids such as D-amino acids, beta-amino acids and ε-amino acids. The vast number of possibilities of a stabilized peptide containing at least one histidine or asparagines is innumerable. The peptide can be a dipeptide, a tripeptide, a tetrapeptide and so on, and can have innumerable number of amino acids. Furthermore, Glucagon is a 29 amino acid polypeptide with a primary amino acid sequence HSQGTFTSDYSKYLDSRRAQDFVQWLMNT. This means that there are 29^{20} different possible sequences comprising the naturally occurring amino acids to test the functionality. As described above, there are non-natural amino acids that also can be substituted, thus, there are innumerable amount of possibilities of Glucagon variants that are functionally equivalent. There is not sufficient amount of examples provided to encompass the numerous characteristics of the whole genus claimed.

11. The description requirement of the patent statute requires a description of an invention, not an indication of a result that one might achieve if one made that invention. See In re Wilder, 736 F.2d 1516, 1521, 222 USPQ 369, 372-73 (Fed. Cir. 1984) (affirming rejection because the specification does "little more than outlin[e] goals appellants hope the claimed invention achieves and the problems the invention will hopefully ameliorate"). Accordingly, it is deemed that the specification fails to provide adequate written description for the genus of the claims and does not reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the entire scope of the claimed invention.

Rejection-35 U.S.C. 102

12. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

13. Claims 1, 4, 6 and 7 are rejected under 35 U.S.C. 102(b) as being anticipated by Gockel et al (Inorganica Chimica Acta, 2001, 323: 16-22).

14. The instant claim is drawn to a stabilized peptide formulation, either in a solution or in a suspension, comprising: (a) a peptide containing at least one histidine residue; (b) a transition metal salt; and (c) a pharmaceutically acceptable organic solvent.

15. Gockel et al teach a cyclic dipeptide C-HisHis, c-GlyCys, c-HisCys and c-CysCys in the presence of zinc nitrate. The reference teaches that the preparative reactions have yielded the compounds Zn(c-HisHis)Cl_2, Zn(c-GlyCys)$_2$, Zn(c-Gly-Cys)$_2$-neocuproin, Zn_2(c-HisCys)$_3$I, and Zn(c-CysCys)(N-methylimidazole)$_2$ (see abstract). The reference further teaches that c-HisHis could be combined directly with the zinc halides. Of these $ZnCl_2$ yielded a pure 1:1 complex soluble in methanol or water (see p. 19, left column, 2nd paragraph). Furthermore, the reference teaches that all species resulting from reactions of c-HisCys and c-CysCys with zinc salts were insoluble precipitates, and only in one case could a specific composition be achieved reproducibly: zinc iodide, c-HisCys and triethylamine in ethanol (see p. 19, left column, bottom (or 3rd) paragraph). Thus, this meets the limitations of claims 1, 4, 6 and 7.

16. Claim 17 is rejected under 35 U.S.C. 102(b) as being anticipated by Krstenansky JL (US Patent # 5789540).

17. The instant claim is drawn to a stabilized peptide formulation, comprising a dried mixture of an acid and a peptide containing at least one asparagine residue.

18. Krstenansky JL teaches a peptide derivative of formula X-A1-A2-A3-A4-A5-A6-A7-A8-A9-A10-Y where in A4, A7, A8 can be Asn (see column 2, lines 11-17). A1 can be TPKPQSHNDGDSTPNPESHNNGDHNDGDNDGDDGDGDD or a bond (see column 4, lines 20-25). The reference teaches peptides with at least one Asn residue (see Examples 2, 3 for example). Furthermore, the reference teaches that the polypeptides can form pharmaceutically acceptable salts with any non-toxic, organic or inorganic acid (see column 3, lines 57-59). Thus, this meets the limitation of claim 17.

19. Claims 1-2 and 4-8 are rejected under 35 U.S.C. 102(b) as being anticipated by Kamei et al (US Patent # 5480868).

20. The instant claims are drawn to a stabilized formulation, either in a solution or in a suspension, comprising: a) a peptide containing at least one histidine residue, (b) a transition metal salt (zinc, copper, iron, manganese, nickel or cobalt), and c) a pharmaceutically acceptable organic solvent (DMSO...propanol, propylene glycol, glycerol acetate...acetic acid...benzyl alcohol...PEG 400), wherein the peptide is selected from the group consisting of PACAP, PACAP-like peptides, VIP, glucagons, GLP, secretin, helodermin, exendin-4, or any functionally equivalent variants thereof, wherein the histidine residue is a terminal histidine residue.

21. Kamei et al teach a sustained release preparation which comprises a physiologically active peptide (see abstract) and examples of the physiologically active peptide may be LH-RH antagonists, insulin, somatostatin, somatostatin derivatives...adrenocorticotropic hormone (ACTH)...secretin...(see column 16, lines 34-60). This reads on claims 2-5. The reference is silent as to the peptide having at least one histidine residue that is a terminal histidine residue. However, since the reference discloses secretin and adrenocorticotropic hormone, the peptide inherently comprises at least one histidine residue as the terminal histidine residue. The reference further teaches that the peptide may be in the form of a metal complex compound (e.g. copper complex, zinc complex, etc). The preferred salts of peptide are salts with organic acids (e.g. carbonic acid...acetic acid, propionic acid, trifluoroacetic acid, etc) (see column 11, lines 12-16). This reads on claims 1 and 6-8.

22. Claims 1-2, 4-8, 34-36, 39 and 41-43 are rejected under 35 U.S.C. 102(b) as being anticipated by Bouman et al (US Patent # 2902408).

23. The instant claims are drawn to a stabilized formulation, either in a solution or in a suspension, comprising: a) a peptide containing at least one histidine residue, (b) a transition metal salt (zinc, copper, iron, manganese, nickel or cobalt), and c) a pharmaceutically acceptable organic solvent (DMSO...propanol, propylene glycol, glycerol acetate...acetic acid...benzyl alcohol...PEG 400), wherein the peptide is selected from the group consisting of PACAP, PACAP-like peptides, VIP, glucagons,

GLP, secretin, helodermin, exendin-4, or any functionally equivalent variants thereof, wherein the histidine residue is a terminal histidine residue.

24. Bouman et al teach a suspension that has the following compositions: Glucagon, zinc, glacial acetic acid, hydrochloric acid, nipagin, sodium hydroxide and distilled water (see Example II); insulin, glucagons, zinc, glacial acetic acid, HCl, nipagin, sodium hydroxide and distilled water (see Example VI); ACTH, zinc, glycerol, phenol, sodium hydroxide and tertiary sodium phosphate (see example VII and VIII) It is well known in the art that glucagons have the amino acid sequence: HSQGTFTSDYSKYLDSRRAQDFVQWLMNT. Thus, this prior art meets the limitation of claims 1-2, 4-8, 34-36, 39 and 41-43.

25. Claims 44-46 and 50 are rejected under 35 U.S.C. 102(b) as being anticipated by Ohsaki et al (US Patent # 5428129).

26. The instant claims are drawn to a process for preparing a stabilized peptide formulation comprising the steps of: (a) preparing an acid solution of acid and water, (b) cooling said acid solution to below room temperature, (c) mixing said cooled acid solution and a peptide containing at least one asparagines residue to create a cooled mixture, and (d) drying said cooled mixture, wherein the acid is HCl. The claims are further drawn to the drying step is freeze-drying or spray-drying.

27. Ohsaki et al (US Patent # 5428129) teach that Boc-Ser(Bzl)-Asn-Leu-Opac (2.11 g) was dissolved in 7 ml of TFA under ice-cooling and the solution was allowed to stand at room temperature for 1 hour. The solution was then ice-cooled again and 4 N

HCl/dioxane (2.5 ml) was added. After shaking, the mixture was treated with diethyl ether and the resulting precipitate was collected by filtration and dried under reduced pressure over potassium hydroxide (see column 27, lines 56-68). This reads on claims 44-46. The reference further teaches that SEQ ID NO:1 was lyophilized to give purified compound (see Example 3). Thus, it is inherent that other SEQ ID NOS would also be lyophilized to recover the purified compound. Therefore, this reads on claim 50. Although the prior art is silent as to cooling the acid solution below room temperature, it is inherent that the acid solution is cooled to the same temperature as the peptide to keep the reaction under the same condition. Additionally, the prior art recites HCl/dioxane solution mixing with the peptide. It is inherent that HCl is made up of mixture of water and acid, therefore, recitation of HCl in the prior art meets the limitation of acid solution of acid and water.

28. Claims 1, 6, 8, 10, and 34-37 are rejected under 35 U.S.C. 102(b) as being anticipated by Pallenberg et al (US Patent # 5538945).

29. The instant claims are drawn to a stabilized peptide formulation, either in a solution or in a suspension, comprising: a peptide containing at least one histidine residue, a transition metal salt and a pharmaceutically acceptable organic solvent wherein the transition metal salt is copper and the pharmaceutically acceptable organic solvent is DMSO.

30. Pallenberg et al teach a peptide-copper complexes, with the second position of the peptide from the amino terminus being histidine, arginine or derivatives of thereof,

and the peptide-copper complexes any be formulated for administration by, for example, topical application or injection (see abstract). The reference teaches the peptide sequences GHKF, PHKF, GHKVFV, GHKVP for example complexed with copper (see table 4). This reads on claim 1 (a), (b) and 34. The reference further teaches that the peptide-copper complexes may also be formulated to contain additional ingredients such as penetration enhancement agents and/or surface active agents. Suitable penetration enhancing agents include DMSO, urea and substituted urea compounds (see column 9, lines 1-4 and 15-18). This reads on claims 1, 6, 8 and 10. Furthermore, the reference teaches that the peptide-copper complexes are formulated for intradermal injection to the treatment area...combination with a suitable vehicle for intradermal injection, with the peptide-copper complex present in the composition at a concentration ranging from 100 μg to 2000 μg per 0.1 ml vehicle (see column 8, lines 41-50) and the peptide-copper complexes are formulated for topical administration, in the form of a liquid, lotion, cream and gel...for topical compositions, one or more peptide-copper complexes are in an amount ranging from 0.1% to 20% by weight of the composition (see column 6, lines 51-54 and lines 63-67). Since the peptide-copper complex can be formulated into different formulations by weight, this implies that peptide-copper complex is in a dried mixture. And as described above, suitable penetration enhancing agents may also be added to the formulation, this reads on claims 34-37. Thus, the prior art reads on claims 1, 6, 8, 10 and 34-37.

31. Claim 26 is rejected under 35 U.S.C. 102(b) as being anticipated by Pan et al (WO 01/23420 A2).

32. The instant claim is drawn to a stabilized formulation, comprising a dried mixture of an acid and PACAP 66 and/or a salt thereof.

33. Pan et al teach insulin secretagogue peptide R3P66 having the sequence HSDAVFTDNYTRLRKQVAAKKYLQSIKNKRY (see SEQ ID NO: 72). The reference further teaches that to synthesize the polypeptides, FMOC/t-butyl strategy was followed and the peptides were precipitated from the cleavage cocktail using cold diethyl ether. The precipitate was washed three times with the cold ether and then dissolved in 5% acetic acid prior to lyophilization (see Example 5). This meets the limitation of claim 26.

Allowable Subject Matter

34. Claims 11-13 and 15-16 appear to be allowable. SEQ ID NO:1 is known in the art, however, a formulation of SEQ ID NO:1, ZnCl2 and pharmaceutically acceptable organic solvent is both novel and unobvious over the prior art. Claims 3, 18, 26, 28-33, 40, 48-49 and 51-53 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

35. Claims 11-13 and 15-16 appear to be allowable. SEQ ID NO: 1 is known in the art, however, a formulation of SEQ ID NO:1, $ZnCl_2$ and pharmaceutically acceptable organic solvent is both novel and unobvious over the prior art. Claims 3, 18, 26, 28-33, 40, 48-49 and 51-53 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. Claims 1-2, 4-8, 10, 17, 19-20, 22-26, 34-37, 39, 41-46, and 50 are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Julie Ha whose telephone number is 571-272-5982. The examiner can normally be reached on Mon-Fri, 8:00 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Julie Ha
Patent Examiner
AU 1654

8/2/07
ANISH GUPTA
PRIMARY EXAMINER